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K120659

510(k) SUMMARY

Submitted by: **Hu-Friedy Mfg. Co., LLC**
3232 N. Rockwell Street
Chicago, IL 60618

NOV 6 2012

Contact Person: **Maria Vrabie, Regulatory Affairs Manager**
Phone: (773) 975-3975 ext. 3495
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Date Prepared: **02/29/2012**
Device Trade Name: **Hu-Friedy Dental Cartridge Syringes**
Classification Name: **Syringe, Cartridge**
Regulation number: **21 CFR 872.6770**
Regulatory Class: **II**
Product Code: **76 EJI**

Device Description:
Hu-Friedy® dental cartridge syringes are made from chrome-plated brass and stainless steel. Syringes are reusable, sterilizable and packaged non-sterile.

Intended Use:
These devices are intended for use by dental professionals only. The devices are indicated to be used in conjunction with anesthetic needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity.

Technological Characteristics:
Hu-Friedy will offer 2 patterns of syringes, the CW type cartridge syringe and the A type cartridge syringe. Both patterns of cartridge syringe are compatible with a standard 1.8ml anesthetic vial. According to ISO 9997:1999, both patterns are classified as type 2a- aspiration by force produced by drawing the plunger away from the needle. The needle mounting threads for both patterns are available in standard imperial threads.

Performance Characteristics:
Results of in-house testing with Hu-Friedy dental cartridge syringes demonstrated that they performed within recommended specifications of the applicable clauses of ISO 9997-Dental Cartridge Syringes, ISO 11499-Dental Cartridges for Local Anesthetics and ISO 13402-Surgical and Dental Hand Instruments. Verification criteria included loading of cartridges, plunger rod testing, plunger movement testing, aspiration testing and corrosion testing.
In addition, Hu-Friedy successfully completed an outside laboratory qualification study of the proposed steam sterilization cycles. The resulting recommended instructions to dental facilities for routine sterilization of the reusable dental syringes conform to ANSI/AAMI ST79.
Predicate Device:

510(k)#	Device	Manufacturer
Pre-amendment	Cartridge Syringes	Henke-Sass Wolf GmbH

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Device Comparison

Criteria	Hu-Friedy Cartridge Syringes	Predicate: Henke Sass Wolf Cartridge Syringes (Pre-amendment)
Indications for Use/ Intended Use	These devices are intended for use by dental professionals only. The devices are indicated to be used in conjunction with anesthetic needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity.	These devices are intended for use by dental professionals only. The devices are indicated to be used in conjunction with anesthetic needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity.
Target Population	Children and adults	Children and adults
Anatomical sites	Oral cavity	Oral cavity
Where used	Dental operatory	Dental operatory
Design	Patterns: • Type A • Type CW	Patterns: • Type A • Type CW
Materials used	• Chrome plated brass and stainless steel	• Chrome plated brass and stainless steel
Compatibility with other devices	• Compatible with industry standard 1.8ml anesthetic vial	• Compatible with industry standard 1.8ml anesthetic vial
Reprocessing and cleaning methods	• Tested in accordance with ANSI/AAMI ST 79	• Tested in accordance with ISO 17664/17665
Sterility	• Product is supplied non-sterile	• Product is supplied non-sterile
Performance Standards Met	• ISO 9997:1999 • ISO 11499:2007 • ISO 13402:1995	• ISO 9997:1999 • ISO 11499:2007 ISO 13402:1995

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 6, 2012

Hu-Friedy Manufacturing, Company, Limited Liability Company
Ms. Maria Vrabie
Regulatory Affairs Manager
3232 North Rockwell Street
Chicago, Illinois 60618

Re: K120659
Trade/Device Name: Hu-Friedy Dental Cartridge Syringe
Regulation Number: 21 CFR 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: II
Product Code: EJI
Dated: October 3, 2012
Received: October 3, 2012

Dear Ms. Vrabie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

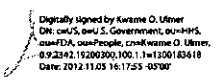
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer



for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K120659

Device Name: **Hu-Friedy® Dental Aspirating Syringes**

Intended Use:

These devices are intended for use by dental professionals only. The devices are indicated to be used in conjunction with anesthetic needles and anesthetic cartridges for injection of anesthetic solutions in the oral cavity.

Susan Runte

(Division Sign-Off)
Division of Anesthesiology General Hospital
Infection Control, Dental Devices

510(k) Number: K120659